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(54) **Suture needle construct for cruciate ligament repair**

(57) A suture needle construct for extracapsular ligament reconstruction in mammals. In a technique for using the suture needle construct of the invention, the joint is first explored, and the damaged ligament and meniscus are debrided. The joint capsule is closed and a tunnel is created at the appropriate location in the proximal tibia for tibial fixation. Subsequent to the formation of the tibial tunnel, the suture needle construct, i.e., a suture with a

substantially curved needle at one end and a substantially straight needle at the other end, is brought in the proximity of the joint. The suture is passed around the lateral fabella using the substantially curved needle, then deep to the patellar ligament using the substantially straight needle, and through the tibial tunnel using the substantially straight needle. The needles are cut off, and the sutures are tensioned over the repair site.

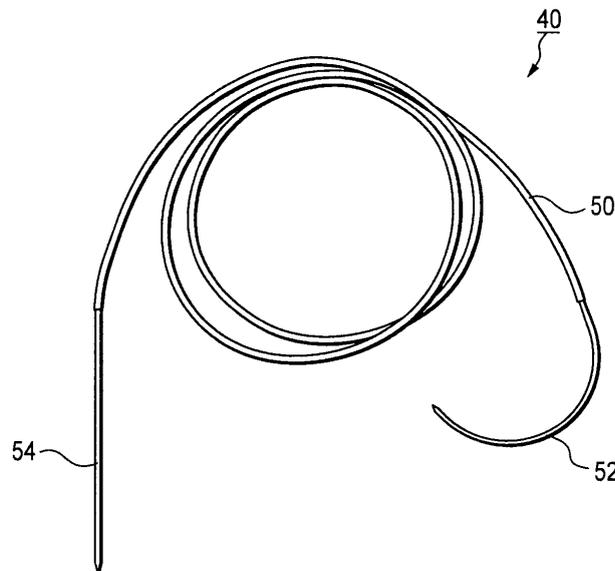


FIG. 1

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Description

[0001] The present invention relates to a suture needle construct for ligament repair and, more specifically, to a suture needle construct for extracapsular ligament reconstruction of mammals, in particular, canines.

[0002] Various improvements in repairing damage to knee joints in human and non-human animals have been made over the years, some of the major advances involving endoscopic techniques and arthroscopic procedures. Arthroscopic surgery is particularly useful in excising or repairing damaged knee cartilage. Endoscopic techniques have been developed for use in repair and reconstruction of damaged anterior cruciate ligaments (ACL) and posterior cruciate ligaments (PCL).

[0003] Cruciate ligament repairs, particularly canine Cranial Cruciate Ligament (CrCL) repairs, are becoming increasingly important. The CrCL attaches to the femur, runs across the stifle joint, and attaches to the tibia. The CrCL holds the tibia in place and prevents internal rotation and hyperextension. CrCL rupture occurs primarily in the knees of dogs and cats, and it is one of the most common orthopedic injuries in dogs. CrCL rupture is also the most common cause of degenerative joint disease in the stifle joint. When a CrCL is torn, it causes sudden pain, instability in the knee joint, and often results in the pet holding its leg up. The pet may put the leg down and start using it within few days, but will continue to limp for several weeks. Typically, at the end of several weeks, the initial pain subsides and the pet will try to use its leg more; however, the joint remains unstable. Every time the animal puts weight on the leg, the tibia slides forward relative to the femur. This abnormal motion causes wear and tear on the joint cartilage, causing pain and leading to arthritis. This motion can also impart excessive stress on the menisci (C-shaped cartilage within the knee joint), causing damage or tearing.

[0004] Surgery is the only corrective measure for CrCL injuries. In the United States alone, the number of canine surgeries per year is estimated to be between about 50,000 to about 100,000, with the most common surgical CrCL repairs being tibial plateau leveling osteotomy (TPLO) and extracapsular repairs. The extracapsular repairs employ suture and represent about 70% of the total repairs. Surgery stabilizes the knee, allowing it to regain normal motion and therefore reducing the formation of arthritis.

[0005] An improved suture needle construct for CrCL reconstruction technique is needed which provides increased fixation strength and optimal tension of the repair.

[0006] The present invention provides a suture needle construct for extracapsular ligament reconstruction in mammals. In the method of using the suture needle construct of the present invention, the joint is first explored, and the damaged ligament and meniscus are debrided. The joint capsule is closed and a tunnel is created at the appropriate location in the proximal tibia for tibial fixation.

The present invention, a suture having a substantially curved needle at one end and a substantially straight needle at the other end is brought in the proximity of the joint. The suture is passed around the lateral fabella using the substantially curved needle, then deep to the patellar ligament (proximal to the tibial tuberosity) using the substantially straight needle, and through the tibial tunnel using the substantially straight needle. The needles are cut off, and the sutures are tensioned over the repair site by using a tensioner, for example. Additional sutures may be provided to close the fascia and the skin.

[0007] Other features and advantages of the present invention will become apparent when the following detailed description is read in conjunction with the accompanying drawings, in which:

[0008] FIG. 1 illustrates the suture needle construct of one embodiment of the present invention, with a substantially curved needle attached to one end and a substantially straight or linear needle attached to the other end.

[0009] FIG. 2 is a lateral view of a canine knee undergoing a method of CrCL reconstruction according to one embodiment of the present invention;

[0010] FIG. 3 illustrates the canine knee at a preparation stage subsequent to that shown in FIG. 2;

[0011] FIG. 4 illustrates the canine knee at a preparation stage subsequent to that shown in FIG. 3;

[0012] FIG. 5 illustrates the canine knee at a preparation stage subsequent to that shown in FIG. 4;

[0013] FIG. 6 illustrates the canine knee at a preparation stage subsequent to that shown in FIG. 5;

[0014] FIG. 7 illustrates the canine knee at a preparation stage subsequent to that shown in FIG. 6;

[0015] FIG. 8 illustrates the canine knee at a preparation stage subsequent to that shown in FIG. 7;

[0016] FIG. 9 illustrates the canine knee a preparation stage subsequent to that shown in FIG. 8; and

[0017] The following description is provided to enable a person skilled in the art to make and use the invention and sets forth the best modes contemplated by the inventors of carrying out their invention. Various modifications, however, will remain readily apparent to those skilled in the art.

[0018] The present invention provides a suture needle construct for extracapsular ligament reconstruction in mammals, for example, CrCL reconstruction. The present invention is a suture with a substantially curved (or substantially non-linear) needle at one end and a substantially straight (or substantially linear) needle at the other end. As described below, the suture is passed around the lateral fabella using the curved needle, then deep to the patellar ligament using the straight needle, and through the tibial tunnel using the straight needle.

[0019] Although the present invention will be described below with reference to an extracapsular canine ligament reconstruction (such as the CrCL reconstruction), the invention is not limited to use in such a procedure. Thus, the suture needle construct of the present invention has

applications to ligament reconstruction in general, and is not limited by the CrCL exemplary technique described below.

[0020] Referring now to the drawings, where like elements are designated by like reference numerals, FIG. 1 illustrates the present invention, a suture needle construct 40 used for CrCL reconstruction. Suture needle construct 40 is formed of a length of suture 50 with a substantially curved needle 52 at one end and a substantially straight or linear needle 54 at the other end. Although FIG. 1 illustrates substantially curved needle 52 as a semicircle having a uniform radius, the invention is not limited to this exemplary embodiment, and contemplates curved needles having various non-linear configurations and geometries, such as an arcuate or bend configuration, or a bow configuration, or a combination of such configurations, among others. Thus, the semicircle configuration shown in FIG. 1 is only exemplary and the invention contemplates other substantially non-linear configurations for the curved needle 52.

[0021] In an exemplary embodiment, at least one of the two needles 52, 54 is a thin nitinol needle that allows an increased number of suture loop passes through, or around, the tissue to be attached or sutured with decreased trauma. Preferably, both needles 52, 54 are nitinol needles; however, other materials such as stainless steel, for example, may be employed for the needles. The needles may be swaged on the suture strand or on the plurality of suture strands. Alternatively, at least one of the needles may be free floating so that, after passing the suture loop construct through the tissue to be treated, one or both of the needles may be reoriented relative to each other.

[0022] Needles 52, 54 may be provided at each end of the suture (as shown in FIG. 1) or, alternatively, may be positioned on the length of the suture (i.e., not necessarily at the ends of the suture) and spaced apart from each other. In other embodiments, one needle may be positioned at one end of the suture whereas the other needle may be positioned anywhere on the length of the suture, as long as the needles are spaced apart from each other.

[0023] In a preferred embodiment, the suture attached to needles 52, 54 is formed of a high strength suture material such as Arthrex FiberWire suture, which is described in U.S. Pat. No. 6,716,234 to Grafton et al. In additional embodiments, the suture may be a FiberWire suture of various colors to maximize repair strength, aid in suture management and provide superior tying characteristics. In an exemplary embodiment, the suture may be a #5 FiberWire, a particular high strength suture sold by Arthrex, Inc. of Naples, Florida, USA. However, the invention is not limited to these exemplary embodiments and it must be understood that the invention contemplates various sizes and dimensions of the suture employed, depending on the size, age and breed of the animal ligament, among other factors. For example, in a canine CrCL repair, a #2 FiberWire is indicated for a

smaller dog, while a #5 FiberWire is indicated for a larger dog such as Bernese mountain dog. Additionally, the invention also contemplates suture materials other than FiberWire, for example, monofilament sutures, Ethibond, or other braided sutures, among many others.

[0024] The suture attached to the needles 52, 54 may be employed as a single strand or as multiple strands, depending upon the size and characteristics of the ligament to be repaired. Thus, a two-strand suture between the two needles provides four strands of suture with one pass, increasing the strength characteristics. Although the invention is described herein as a single strand of high strength suture 50 that is attached to needles 52, 54, the invention is not limited to this embodiment and encompasses embodiments where a plurality of continuous strands of suture 50, or continuous loops of suture 50, or a combination of continuous strands of suture 50 and continuous loops of suture 50, are attached to the two needles.

[0025] The method of ligament repair using the suture needle construct 40 of one embodiment of the present invention will be described below with reference to a particular exemplary embodiment. In this particular exemplary embodiment, the tissue to be treated is a canine CrCL that is repaired by passing the suture needle construct 40 of one embodiment of the present invention. Although the invention will be described with reference to this particular exemplary canine embodiment, it must be understood that the invention is not limited to this embodiment and contemplates ligament repairs in other mammals, such as cats, horses or cows. In addition, the invention also contemplates treatment (such as suturing or attachment, for example) of any ligament and tissue with the suture needle construct 40 described above. For example, the suture needle construct 40 may be employed to simply put stitches in a graft, in preparation for fixation with a fixation device such as an interference screw.

[0026] According to an exemplary embodiment, the tissue to be treated is a canine CrCL. FIGS. 2-9 illustrate the interior of a canine knee 90 in a lateral perspective undergoing the method of CrCL reconstruction using suture needle construct 40 of FIG. 1 according to the present invention. The joint is first explored and preparation of the knee cavity is conducted by removing any remaining articular cartilage using a combination of a rasp, curette and mechanical burr, for example. The patient is positioned in lateral or dorsal recumbency preferably under general anesthetic. A hanging limb technique with aseptic preparation and appropriate draping may be performed. A lateral parapatellar approach with arthrotomy may be performed and complete exploration of the stifle joint may be conducted. Pathologic ligament and meniscus should be treated appropriately. Once the joint is thoroughly lavaged, the joint capsule may be closed.

[0027] Referring now to FIG. 2, after the joint capsule is closed, a combination of sharp and blunt dissection is

used to separate the vastus lateralis and biceps femoris muscles and retract the biceps caudally, to allow for exposure and palpation of the lateral fabella (pin 91 pointing to it).

[0028] Suture needle construct 40 having a substantially curved needle 52 at one end of suture 50, and a substantially straight needle 54 at the other end of suture 50, is brought in the proximity of the joint. The substantially curved needle 52 is then placed with the tip on the midpoint of the lateral fabella and "walked" proximally until it can be inserted between the fabella and femur and passed completely around the fabella from proximal to distal. In this manner, the suture 50 is passed around the lateral fabella using the substantially curved needle 52, as shown in FIG. 3.

[0029] As shown in FIG. 4, the substantially curved needle 52 is preferably around the fabella and not caudal to it. This can be verified after suture placement by pulling on both strands of the suture 50 to ensure they are around the bone of the fabella and not soft tissues caudal to it. It is also important to minimize the amount of soft tissue encompassed in the suture throw, paying particular attention to the peroneal nerve distally. The substantially curved needle 52 is designed to help promote correct placement.

[0030] Reference is now made to FIG. 5. The substantially straight needle 54 at the opposite end of suture 50 is then passed deep to the patellar ligament from lateral to medial at the most distal point. At this point, the suture 50 should be caudal to the ligament and cranial to the fat pad.

[0031] A hole (also referred to as "tunnel" or "socket") of about 2-3 mm is next created at the appropriate location in the proximal tibia for tibial fixation (FIG. 6). Preferably, the location of the tibial tunnel should be distal to Gerdy's tubercle and proximal to the point of origin of the cranial tibial muscle. The tibial tunnel should be slightly angled caudoproximal to craniodistal to match the final direction of the suture 50. The tibial tunnel may be formed by employing a drill 60 (FIG. 6), for example, to allow the substantially straight needle 54 to be inserted through the tibial tunnel, as shown in FIG. 7.

[0032] As the pin or drill is removed, the straight needle 54 of the suture needle construct 40 is inserted in the tibial tunnel from medial to lateral, and suture 50 is advanced to allow for easy tying.

[0033] As shown in FIG. 8, both needles 52, 54 are cut off and the suture 50 is tied at the desired tension, to prevent abnormal cranial drawer and internal rotation. The stifle is then put through a range of motion to ensure the suture has been placed correctly and is not impinging on periarticular structures. The area may be lavaged. The ends of suture strand 50 are tied and tensioned over the repair site by using a tensioner, for example, to tension the suture knot to a specific poundage.

[0034] Referring to FIG. 9, the lateral fascia is closed with the imbricating pattern of choice. Routine subcutaneous tissue and skin closures may be performed. Ad-

ditional sutures may be provided to close the fascia and the skin.

[0035] Although the present invention has been described above with reference to an exemplary CrCL repair, the invention is not limited to use in this exemplary technique. Those skilled in the art will recognize that the structures and techniques disclosed can be used for ligament repair generally. Thus, the suture needle construct 40 of an embodiment of the present invention can be used in various in tissue repairs, such as ligament repair, i.e., simple suturing of tissue, tendon to tendon repair, graft to bone repair, or tendon to bone repair, among others.

[0036] In addition, although the present invention has been described in connection with preferred embodiments, many modifications and variations will become apparent to those skilled in the art. Thus, it is not intended that the present invention be limited to the illustrated embodiments. Any modification of the present invention which comes within the scope of the following claims should be considered part of the present invention.

Claims

1. A suture needle construct, comprising:
 - a suture strand;
 - a substantially curved needle disposed at a first location on the suture strand; and
 - a substantially linear needle disposed at a second location on the suture strand.
2. The suture needle construct of claim 1, wherein the suture strand comprises a plurality of suture strands.
3. The suture needle construct of claim 1 or claim 2, wherein the curved needle and the linear needle are disposed on opposite ends of the suture strand.
4. The suture needle construct of any preceding claim, wherein the suture strand comprises a high strength suture.
5. The suture needle construct of any preceding claim, wherein at least one of the substantially curved needle and the substantially linear needle is a nitinol needle.
6. The suture needle construct of any preceding claim, wherein the substantially curved needle has a semi-circular configuration.

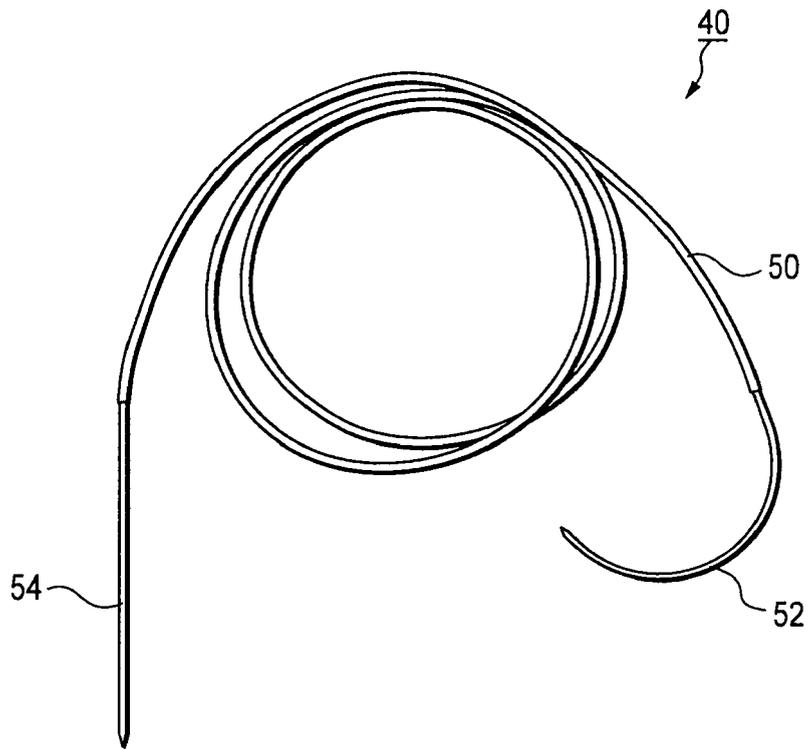


FIG. 1

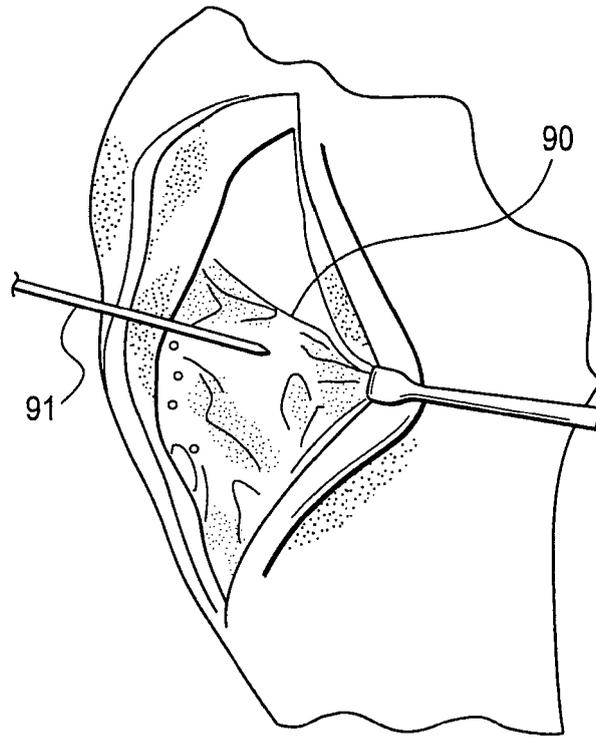


FIG. 2

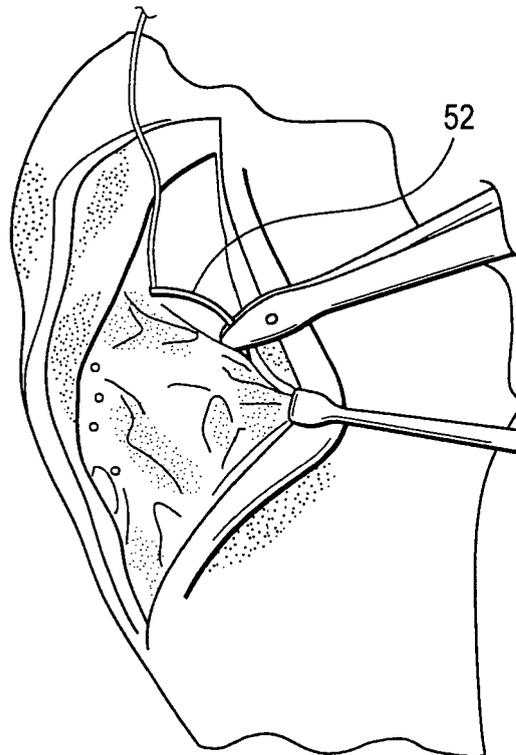


FIG. 3

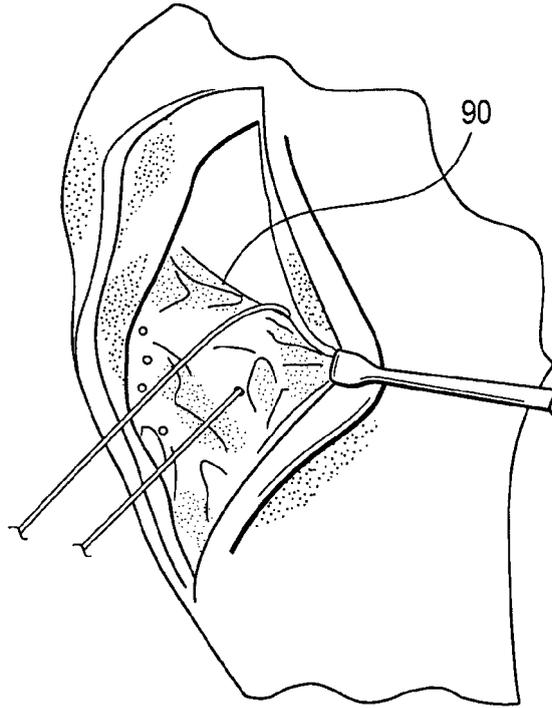


FIG. 4

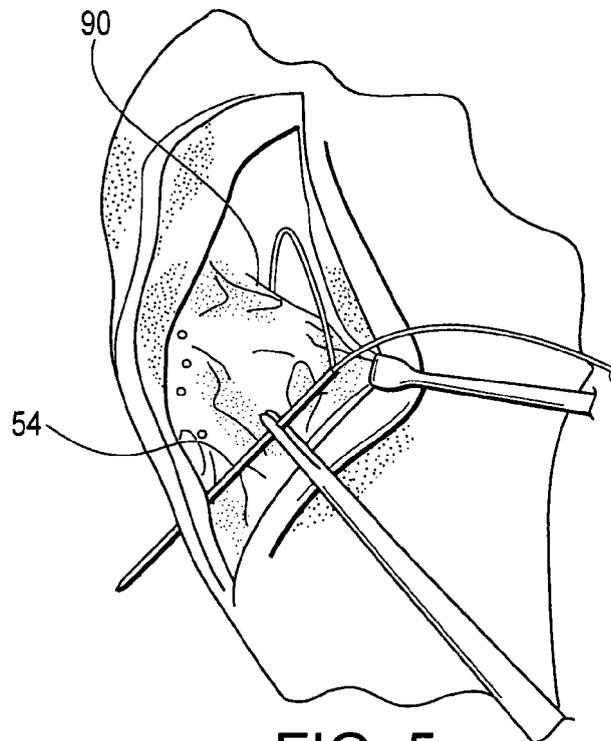


FIG. 5

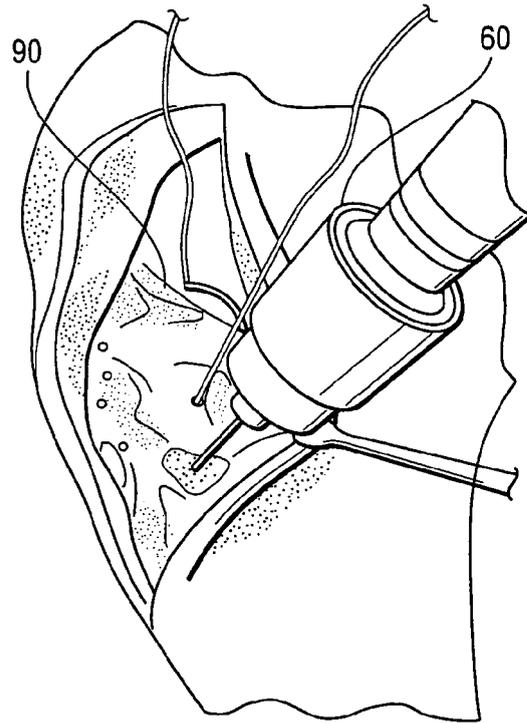


FIG. 6

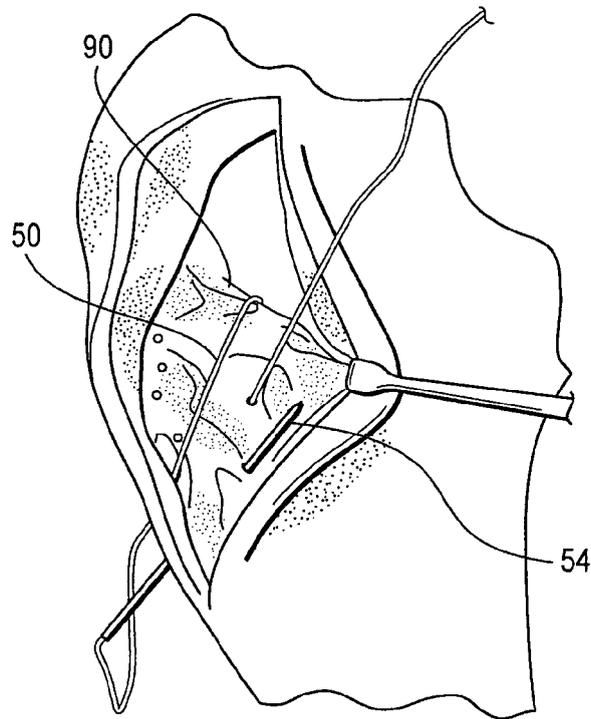


FIG. 7

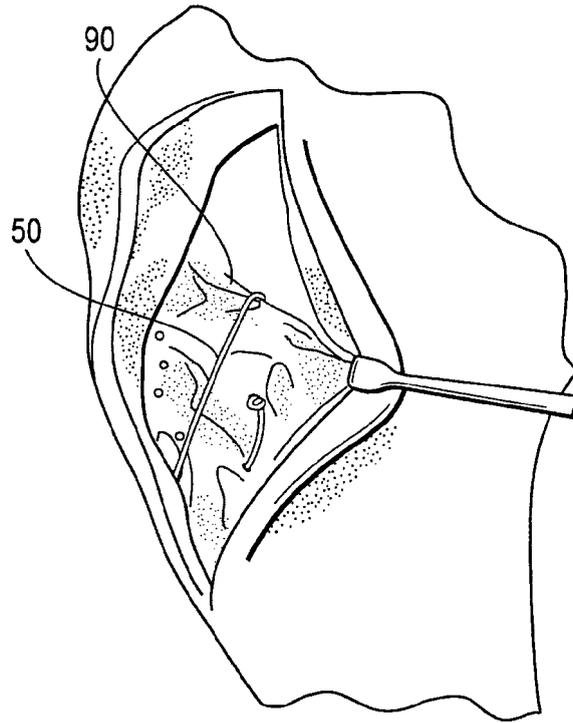


FIG. 8

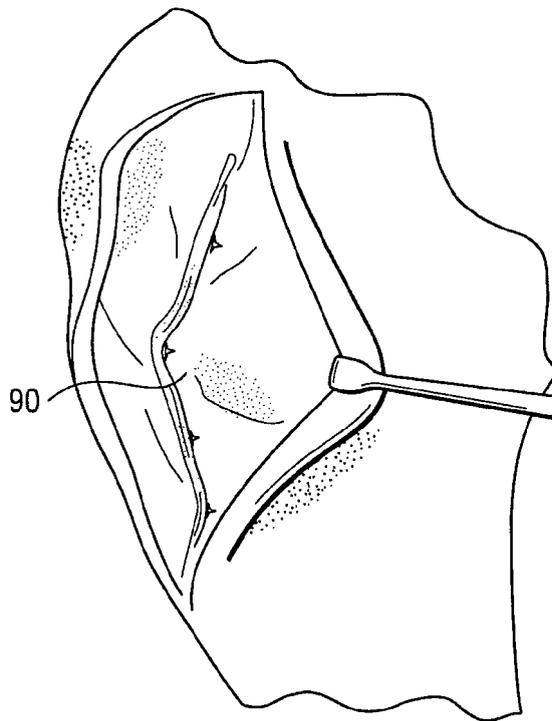


FIG. 9



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| Place of search The Hague | | Date of completion of the search 19 February 2007 | Examiner GIMENEZ BURGOS, R |
| CATEGORY OF CITED DOCUMENTS X : particularly relevant if taken alone Y : particularly relevant if combined with another document of the same category A : technological background O : non-written disclosure P : intermediate document | | T : theory or principle underlying the invention E : earlier patent document, but published on, or after the filing date D : document cited in the application L : document cited for other reasons & : member of the same patent family, corresponding document | |

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**ANNEX TO THE EUROPEAN SEARCH REPORT
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